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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,571	01/29/2004	Karla Weaver	10123/00701	6350
<div>7590 11/21/2007</div> <div>Patrick J. Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038</div> <div>EXAMINER STIGELL, THEODORE J</div> <div>ART UNIT 3763 PAPER NUMBER</div> <div>MAIL DATE 11/21/2007 DELIVERY MODE PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/768,571

Applicant(s)

WEAVER ET AL.

Examiner

Theodore J. Stigell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/6/2006, 1/10/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-7 and 10, 12-14, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Frisch *et al.* ('237).
2. Frisch *et al.* discloses a valve housing (511), a flexible membrane (84) and a slit (83). (See Figure 7 and 8) Frisch *et al.* discloses coating all blood contacting surfaces with a suitable anticoagulant material such as TDMAC-heparin. (See Column 12 Lines 15-30) The flexible membrane is disclosed to comprise silicone. (See Claim 2)
3. As to claim 10 and 12-13, Frisch discloses an elongated body (41), a lumen (not referenced), a valve (511), and an anticoagulant coating comprising heparin (not referenced). (See Figure 6-8) The valve comprises a flexible membrane, such as silicone, and a slit (83).
4. As to claim 14 and 16-17, Frisch *et al.* disclose a lumen (not referenced), a housing (511), a valve (513), a slit (83) and an anticoagulant coating comprising

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heparin (not referenced). (See Figure 6-8) The valve is taught to be under a sufficient amount of pressure to seal against a pressure of at least 300 mm Hg from the blood.

(See Claim 11)

5. Thus it appears that Frisch *et al.* reasonably teaches every element of claims 1-7 and 10-17.

6. Claims 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Steigerwald ('391).

7. Steigerwald disclose a valve comprising a valve housing (22), a plurality of flexible members (90, 94) with at least one slit (92a-c, 96a-c) and a fluid directing recess (24). (See Figure 5 and 6)

8. Thus, Steigerwald appears to reasonably disclose every element of claims 18 and 21.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch *et al.* ('237) in view of Steigerwald ('391).

12. Frisch *et al.* discloses a valve housing (511), a flexible membrane (84) and a slit (83). (See Figure 7 and 8) Frisch *et al.* discloses coating all blood contacting surfaces with a suitable anticoagulant material such as TDMAC-heparin. (See Column 12 Lines 15-30) The flexible membrane is disclosed to comprise silicone. (See Claim 2)

13. Frisch *et al.* fails to disclose abutting flexible membranes.

14. Steigerwald teaches abutting two flexible membranes adjacent to one another. (See Fig. 4d.)

15. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Frisch *et al.* with the teachings of Steigerwald to provide a valve with abutting flexible membranes.

16. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steigerwald ('391) in view of Frisch *et al.* ('237).

17. Steigerwald disclose a valve comprising a valve housing (22), a plurality of flexible members (90, 94) with at least one slit (92a-c, 96a-c) and a fluid directing recess (24). (See Figure 5 and 6)

18. Steigerwald fails to disclose a nonthrombogenic coating on the fluid contacting surfaces.

19. Frisch *et al.* teaches coating all blood contacting surfaces with a suitable anticoagulant material such as TDMAC-heparin. (See Column 12 Lines 15-30)

20. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Steigerwald with the teachings of Frisch *et al.* to provide a valve with a nonthrombogenic coating to prevent blood clotting.

Response to Arguments

Applicant's arguments filed 12/12/2006 have been fully considered but they are not persuasive. In response to the applicant's argument that the references do not teach a flexible membrane that can be moved between a closed and opened configuration

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based on fluid pressure, the examiner respectfully disagrees. If the fluid pressure is high enough, any slit valve can be opened by fluid pressure.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Theodore J. Stigell


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